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Department of Health and Human Services
Food and Drug Administration
Division of Dockets
5630 Fishers Lane
Room. 1061
Rockville, Md. 20852

Ref: Docket No. 2004N-0184 – Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food.

To whom it may concern;

Anresco,Inc. (1943) is a commercial analytical laboratory with headquarters in San Francisco, California and with branch laboratories in Fort Lauderdale, Florida and Los Angeles, California. Anresco has performed sampling and analysis services to satisfy FDA import requirements since 1981 and today performs more analytical work to satisfy FDA import requirements than any other commercial laboratory in the USA. Anresco has been a member of the ACIL (formerly American Council of Independent Laboratories) for more than 30 years.

The public and the import community is best served when FDA regulations relating to food and related imports are meaningful, effective and enforced equitably.

Anresco has encountered many situations where legitimate importers and private laboratories have been placed at a severe disadvantage when FDA regulations have been inadequate to assure an honest system and also when the FDA has failed to enforce its existing regulations consistently between its various Districts.. Inadequate enforcement of FDA regulations has been in part due inadequate staffing and information resources. This problem is less severe today than in the past due to staff increases at FDA during the past 2 years. The FDA has also, however, failed to allocate its limited resources between the various Districts so these reflect the actual volumes of import volume at the various ports of entry to the USA. The FDA also fails to take sufficient "Surveillance" samples of importers petitioning to be exempted from Detention Without Physical Examination and often seems to take no samples after a firm is exempted. These and many other issues (i.e. adequacy of FDA sampling guidelines etc.) are not addressed by the Proposed Rules (Docket No. 2002N-0085) and must be considered administratively or by additional rule making.

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The referenced Docket does standardize for the country the FDA rules governing the sampling and analysis of food imports by private laboratories, the taking of samples by sampling services and the taking of samples by importers themselves.

Anresco believes that if the Proposed Rules are implemented, the changes will result in a substantial improvement in the legitimacy of the data submitted to the Agency pursuant to the Detention Without Physical Examination Program. We feel, however, the FDA should take even more measures to assure the program functions legitimately.

First, Anresco fully supports the following changes the FDA has proposed:

1. That the importer must advise the FDA in advance of any sampling and commercial analytical laboratories it intends to employ to provide data to the FDA. The importer should specify the precise time, location and date of sampling so FDA can be present if it chooses to be and so FDA can compare analytical reports when they are submitted with the importers advance notice to the Agency.

2. That any commercial analytical laboratory generating data for submission to the FDA in connection with a given import sign a statement to accompany any submission of data to the effect that the submission represents all data generated for that import, as per the existing Statements included in FDA Exhibit 21-B of Chapter 21- Guidance on the Review of Analytical Data Generated By Private Laboratories. (Signing this Statement could be unnecessary if the FDA requires the importer to provide advance notice of planned sampling).

These changes will assure importers do not have sampling and analysis performed multiple times to obtain results they believe will be acceptable to the FDA. These changes will only be meaningful, however, if reputable commercial laboratories and sampling organizations are performing the work.

Anresco recommends the FDA include additional rules:

1. The FDA should implement consistent sampling requirements for all Districts. Importers should no longer be allowed to take their own samples for use in generating analytical data for submission to the FDA. This represents an inherent conflict of interest.

2. The FDA should require that all independent samplers and commercial analytical laboratories providing analytical data to the Agency pursuant to its Detention Without Physical Examination Program (DWPE) be certified or accredited both with regard to technical capability and also with regard to financial responsibility before they can participate in this program..Standards for certification or accreditation must be standardized for the entire country.

Anresco believes it would be more meaningful for the FDA to certify or accredit independent samplers and commercial laboratories than to have other accrediting organizations do so . If the FDA continues to believe this impossible, Anresco would support mandatory accreditation by private accrediting organizations acceptable to the FDA.

Anresco believes for accreditation to be meaningful FDA must negotiate Memorandums of Understanding (MOUs) or something similar with the private accrediting organizations.

The FDA should then have commercial analytical laboratories perform much of the routine analytical work the FDA currently performs pursuant to its "Surveillance" programs. The GAO recommended this in its Report on FDA's Seafood Safety Program released in January 2004. This would allow the FDA to examine a much larger percentage of imports than currently thereby better serving the American consumer.

It should also allow private laboratories to submit only basic reports without supporting chromatograms etc. with an understanding the FDA could request these for specific imports as needed. This would save the FDA a great deal of time in reviewing every detail of private laboratory reports submitted pursuant to the DWPE Program.

3. More important than certification or accrediting, Anresco believes the FDA must require a bond and/or professional liability insurance for samplers and commercial analytical laboratories participating in the Program. Insurance companies will not insure irresponsible and incompetent service providers.

Currently, the FDA permits independent sampling and laboratory analysis with limited formal review of the technical qualifications of the sampler or laboratory and no review of their financial responsibility. Sampling is more important and critical than analysis though both functions must be performed independently and with technical competence.

4. The FDA must also provide commercial analytical laboratories formal recourse if and when the FDA becomes dissatisfied with data that is submitted. Currently, the FDA may disqualify private laboratories from the DWPE Program on an "at will" basis and further the Agency also often communicates analytical deficiencies to importers at the same time or before advising the laboratory of such deficiencies. This places legitimate commercial janalytical laboratories in an impossible professional liability situation when oftentimes no real deficiency exists.

As part of the accreditation program, the FDA must develop procedures to provide participating laboratories with due process so they will not be disqualified from the DWPE Program without an established appeals process.

5. The FDA should establish a joint FDA /private laboratory committee to provide for a conduit of information to the private laboratories and from the private laboratories back to the Agency. This would improve trust and in time yield significant improvements in the DWPE Program.

In submitting these Comments Anresco wants to emphasize that the FDA consider it in its entirety. Requiring laboratories to sign Director's Statements that the work submitted represents all work performed on a sample is only meaningful if all laboratories submitting results are responsible (i.e. certified or accredited). Otherwise, if the FDA requires a Director's Statement legitimate laboratories will be placed at a critical disadvantage to illegitimate ones.

Thank you for considering these views.

ANRESCO,INC.

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